

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

| | | | |
|---|--|--|---|
| | | | Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet) |
| Applicant's or agent's file reference see form PCT/ISA/220 | | FOR FURTHER ACTION See paragraph 2 below | |
| International application No. PCT/US2004/009971 | International filing date (day/month/year) 01.04.2004 | Priority date (day/month/year) 01.04.2003 | |
| International Patent Classification (IPC) or both national classification and IPC A61F2/24 | | | |
| Applicant COOK INCORPORATED | | | |

ENTERED
2/10/05

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | | |
|--|---|---|
| Name and mailing address of the ISA:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Newman, B Telephone No. +49 89 2399-6035 |  |
|--|---|---|

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2004/009971**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material:

- a sequence listing
 table(s) related to the sequence listing

b. format of material:

- in written format
 in computer readable form

c. time of filing/furnishing:

- contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.

3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/009971

Box No. II Priority

1. The following document has not been furnished:

- copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
- translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application,
 claims Nos. 26 - 42

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
 the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 no international search report has been established for the whole application or for said claims Nos. 26 - 42
 the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form has not been furnished

does not comply with the standard

the computer readable form has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/009971

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|------|-----------------------------------|
| Novelty (N) | Yes: | Claims 15 - 23 |
| | No: | Claims 1 - 14, 24, 25, 43 |
| Inventive step (IS) | Yes: | Claims 16, 19 - 23 |
| | No: | Claims 1 - 15, 17, 18, 24, 25, 43 |
| Industrial applicability (IA) | Yes: | Claims 1 - 25, 43 |
| | No: | Claims 1 - 25, 43 |

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. According to Rule 67.1 PCT the International Preliminary Examination Authority, in the present case, the EPO, is not required to carry out an international preliminary examination if the subject-matter of the international application relates to methods of treatment of the human or animal body by surgery or therapy as well as diagnostic methods. This is the case for claims 26 - 42.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following documents:

D1: US 6254636 (Peredo)
D2: WO 00/64381 (St. Jude Medical)
D3: WO 01/64137 (Figula)
D4: US 6364905 (Casgrande)
D5: US 2002/138138 (Yang)

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (the references in parentheses applying to this document):

A percutaneous vascular valve (column 1, lines 6 - 9), comprising: a stentless vascular valve body (column 1, lines 6 - 9) having at least one flexible member for restricting blood flow, the flexible member having an edge for contacting a wall of a vascular vessel, said edge adapted to attach to said wall (figure 4).

- 3.2 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 43, which therefore is also considered not new.

- 3.3 These features are also disclosed in documents D2 - D4.
4. Dependent claims 2 - 15, 17, 18, 24 and 25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1 - D5 and the corresponding passages cited in the search report.
5. The combination of the features of dependent claims 16 and 19 - 23 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows: A combination of the features of the prior art documents do not lead directly to the features of these claims. The features of the claims relate to the problem of holding the valve securely on a deployment device. This problem is not mentioned in the documents D1 - D5 and there are no indications of possible solutions.

Re Item VII

Certain defects in the international application

- 6.1 The independent claims should have been drafted in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 6.2 Claim 12 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT).
- 6.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).